Remarks

Claims 1-26 are pending, including newly added claims 24-26. Claims 1 and 22-25 are in independent form.

Claim 20 has been amended to more particularly point out and distinctly claim the invention.

Claim Rejections - 35 U.S.C. 102

Claims 1-3, 5-9, and 20-23 have been rejected under 35 U.S.C. 102 (b) as anticipated by Chen (US 2005/0027371). It is submitted that claim 1 as amended is novel and inventive in light of Chen.

The remarks hereinafter go into considerable detail as to why Chen does not anticipate or make obvious the presently claimed invention. Beyond that, Applicants point out from MPEP 2121.01, "In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure'..." *In re Hoeksema.* Applicants claim 1, for example, describes a coupling body that can articulate only when a bending and/or torsional force applied to the prosthetic limb exceeds a predetermined threshold safe level. It is submitted that (a) Chen describes a structure which is fixed, or if screws are disassembled, is movable, but not a structure which is fixed, then permits accommodation of a bending and/or torsional force, (b) the Examiner introduces interpretations based on loose screws and breaking parts, but (c) there is no disclosure in Chen which would teach, suggest to, or assist one skilled in the art to assemble the elements of the present claims or achieve their benefits. Chen itself is not enabling. This shortcoming is equally applicable to the rejections under section 103, since it limits what Chen can be said to teach.

Indeed, the teaching of Chen is contrary to that of the present invention, as Chen describes a structure built to remain firmly and exclusively fixed.

Claim 1 has been amended to recite that the proximal and distal components are coupled "moveably with respect to each other in at least one of a tilting or an axial rotational manner, said coupling body including a mechanism for holding the components in a fixed relationship to each other for normal use of the prosthetic limb and for allowing the components automatically to move in said at least one tilting or axial rotational manner only when, in use, at least one of a bending and torsional force is applied to the prosthetic limb only when the force exceeds a predetermined threshold safe level". As detailed below, Applicants submit that this language completely avoids the Examiner's interpretation that Chen can anticipate by breaking or bending under a force or by moving because of a loose screw.

Chen does not disclose a failsafe device in which the proximal and distal component can rotate or bend relative to one another only when a force above a predetermined threshold safe level is applied, as recited by claim 1. The Examiner has not given his reasoning as to which particular features of Chen disclose the recited features of claim 1. From the picture on page 4 of the Office Action, we presume the Examiner is referring to possible rotation/ bending of lower connecting piece 12 relative to upper connecting piece 11, which are secured together by screw 13. We note that the Examiner contends that the upper and lower connecting pieces 11, 12 in Chen could rotate/bend relative to one another when "the screws are not tight" (see page 2 of the Office Action).

Whatever the tightness of the screw 13 in Chen, there cannot be any accommodation of a bending force by bending articulation within the apparatus, as threaded engagement of screw 13 in threaded recess 111 would prevent bending of connecting pieces 11 and 12 relative to one another. The only way in which the angle between connecting pieces 11 and 12 could be adjusted is if screw 13 breaks or breaks out of its threaded hole 111, in which case force is not being "accommodated by bending articulation within the attachment apparatus" as there is no bending joint formed between the connecting pieces 11 and 12.

It should be noted that the serrations in the serrated top and bottom surfaces 112, 123 are parallel with each other, not radial, as in the clutch-like mechanism described in the present application. The serrations in the top and bottom surfaces 112, 123 are taught by Chen to be aligned parallel with one another (figures 5 to 7), so that they will interlock to hold the mating pieces fixed. There is no teaching of any other alignment, since it would be completely counterproductive to the purpose of the serrations and would make no sense. Accordingly, no other alignment is relevant for consideration of patentability.

In order to allow any rotation of connecting piece 12 relative to connecting piece 11 in Chen, screw 13 would need to be loose enough to provide at least a gap of twice the depth of the serrations between the plane passing through the base of the troughs of the serrations in the top surface 112 and the plane passing through the base of the troughs of the serrations in the bottom surface 123, in order to physically allow space for the sloping faces of the serrations to slide past one another and for the serrations in the top and bottom surfaces 112, 123 to disengage from their parallel, interlocking configuration. However, leaving a gap between serrated top and bottom surfaces 112, 123 goes against the disclosure of how the apparatus of Chen is assembled, which is that screw 13 is screwed tight (see paragraph 0018) in order that the selected relative position of the upper and lower limb parts does not vary during walking. If the screw 13 were not tight, and there was a gap of at least twice the depth of the serrations between the troughs of the serrations in the top surface 112 and the troughs of the serrations in the bottom surface 123, then the upper and lower connecting pieces 11,12 would move relative to one another during walking, and the patient would lose their balance due to the relative movement of connecting pieces 11,12. If the screw were tightened such that the gap between the troughs of the serrations in the top surface 112 and the troughs of the serrations in the bottom surface 123 is less than twice the depth of the serrations, then the serrated top and bottom surfaces 112 would not be able to rotate relative to one another, as the serrations in the top and bottom surfaces 112, 123 would interlock, but there would be no space to allow the sloping faces of the serrations to slide past one another. There is no means in the device of Chen to allow the screw 13 to be tightened to a precise level that would allow rotation of one connecting piece 11,12 relative to the other only when a force above a certain level is applied, therefore the invention of claim 1 is not disclosed in Chen.

Even if it were possible to tighten the screw to a precise level, wherein the gap between the top and bottom surfaces 112,123 is precisely the correct distance to allow rotation of one connecting piece 11,12 relative to the other only when a force above a certain level is applied, the connecting pieces 11,12 would not rotate relative to one another if any compressive forces, as well as torsional forces, were being applied relative to the apparatus, as the compressive forces would prevent the sloping faces of the serrations of top and bottom surfaces 112, 123 from sliding past one another. Compressive forces would be applied relative to the apparatus, during normal use of the apparatus in a lower limb prosthesis.

For the reasons given above, Chen is clearly not able to be used as a failsafe device, as recited in the independent claims.

The purpose of Chen is to have upper and lower limb parts which are fixed and non-movable to each other during walking, but wherein the apparatus can be adjusted when not in use. With prosthetic lower limbs, it is important that the prosthesis is aligned correctly relative to the knee or ankle below, so that weight can be aligned correctly through the joint during walking to maintain balance during walking. The apparatus of Chen therefore allows lateral adjustment of the upper and lower connecting pieces, when the apparatus is not in use, to maintain balance during resumption of walking (see the end of paragraph 004 and paragraph 005).

For the avoidance of doubt, we point out that it would not be possible for upper limb part 2 of Chen to rotate or bend relative to upper connecting piece 11. A tongue 113 of upper connecting piece 11, having square shaped cross-section, is received in square shaped recess 21. It would not be possible for the square tongue 113 to rotate within the square recess 21. Furthermore, since the tongue 113 is retained in recess 21 by screws 24 arranged on opposing sides, it would not be possible for tongue 113 to bend relative to recess 21, once inserted.

Claims 1 and 22-23 have been amended to recite (and new claims 24, 25 include), "only when the force exceeds a predetermined threshold safe level", as described in the present

application as filed at page 2, line 24 and in its claims 3 and 23. Applicants disclose structure for achieving the controlled, predetermined threshold at pages 7, line 28 through page 8, line 21. For the purposes of a failsafe prosthetic attachment apparatus, it is advantageous to have the threshold force be substantially predetermined. Structure providing a predetermined threshold safe level is not disclosed or suggested by Chen; nor is it represented by a destructive force to which the Examiner makes reference.

The remarks addressed to claim 1 are applicable to claims 22 and 23. The dependent claims are novel and inventive in light of Chen by means of their dependency on claim 1.

Claim 24 is novel and inventive in light of Chen. The apparatus of Chen does not include "adjustment means whereby the threshold safe level of force on the prosthetic limb that will cause said at least one of bending and rotational articulation within the articulation apparatus may be increased or decreased", as recited by 24.

The Examiner contends on page 2 of the Office Action that in Chen, "the locking member will set the threshold level for force to cause movement along with a biased state". The Examiner also contends in relation to claim 5 that "adjustment means whereby the threshold level or torque on the prosthetic limb that will cause disengagement of the clutch-like mechanism may be increased or decreased" as recited in claim 5 is anticipated by screw 127 in Chen. However, applicant respectfully submits that there is no mechanism disclosed in Chen for adjusting any threshold safe level of force above which proximal components of the device may bend/rotate relative to one another. Screw 13 cannot be used to adjust any threshold safe level of force that will cause bending/rotational articulation of the apparatus; as is described above, threading of screw 13 tightly would prevent connecting pieces 11,12 from being able to rotate relative to one another, and decreasing the extent that screw 13 is screwed into recess 111 would cause connecting pieces 11,12 to rotate freely relative to one another, not to rotate only when a torsional force above a certain level is applied. Screw 127 cannot be used to adjust any threshold safe level of force that will cause bending/rotational articulation of the apparatus, as screw 127 is merely for use in securing lower connecting piece 12 to lower limb part 3 (screw 127 in figure 2

has the same purpose as screw 45 in figure 1, which is described in paragraph 0004 of Chen as a horizontal lock bolt 45 that "is screwed tight to lock the lower limb part 6 on the connecting piece 4"). Thus, neither screw 13 or screw 137 can be used to adjust any threshold safe level of force.

Claim 25 is novel and inventive in light of Chen for the reasons given above in relation to claims 1 and 24. In addition, claim 25 recites "resilient biasing means whereby the proximal and distal components are biased in a fixed configuration in which the proximal and distal components are in a fixed angle and rotational relation to one another, wherein the biasing force applied by the resilient biasing means in use determines the threshold safe level of force on the prosthetic limb that will cause said at least one of bending and rotational articulation within the attachment apparatus". There is no disclosure in Chen of any means for resiliently biasing the proximal and distal components toward a fixed angle configuration (i.e. with one component axially aligned with or at a fixed angle of incline to the axis of the other) or toward a rotationally coupled configuration. In contrast, in Chen, connecting pieces 11,12 are attached together by screw 13, and connecting pieces 11,12 are not resiliently biased into a particular configuration.

New claim 26 is novel and patentable in view of Chen for the reasons given in connection with claim 1 and additionally for reasons given in connection with claim 25 with respect to the recited "resilient biasing means". It additionally recites the mechanism that "the resilient biasing means opposes the effect of a force urging the limb toward bending or rotational articulation", which is not shown or suggested by Chen.

For the reasons given above, it is submitted that independent claims 1 and 22-25 are neither anticipated by Chen, nor obvious in view of Chen. Claims 2, 3, 5-9, 20-21, and 26, dependent on claim 1, are submitted to be patentable for the reasons given in connection with claim 1.

Claim Rejections - 35 U.S.C. 103

Claims 4 and 10-19 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in view of Capper et al (US 6,605,118) hereinafter "Capper". It is submitted that Chen and Capper do not show or suggest the features of claims 4 and 10-19. It is submitted that none of the claims are unpatentable over Chen in view of Capper.

The operation of the clutch in Capper is to prevent a locking gear 86 from rotation, thereby locking down a lock pin 60 of a prosthetic attachment locking assembly. The locking gear 86 is held in an axial locking position by a spring. When it is desired to remove the prosthetic, the gear 86 is pushed away from the locking position, so that the locking pin 60 is free to be removed axially.

Claim 4 is dependent on claim 3, which recites "a clutch-like mechanism to rotationally couple the prosthetic limb to the bone implant". Among other differences, the Capper apparatus is for longitudinal coupling. Claim 4 recites "the clutch-like mechanism is resiliently biased to the rotationally coupled state and whereof the biasing force applied to the clutch-like mechanism by the resilient biasing means in use determines the threshold level of torque on the prosthetic limb that will cause disengagement of the clutch-like mechanism". Since Capper does not deal with rotational coupling of the limb, its spring does not bias the clutch to a rotational state of the limb, nor does it determine any level of torque on the prosthetic that will cause disengagement. In Capper, there is no disclosure or suggestion of torque on the limb; a button is pushed to disengage from the connector pin and the prosthetic is removed longitudinally.

Claim 10 recites "the biasing force applied to the disengageable connector by the resilient biasing means in use determines the threshold level of bending force on the prosthetic limb that will cause disengagement of the disengageable connector". Capper makes no disclosure or suggestion of a bending force on the limb that will cause disengagement of the connector. In Capper, a button is pushed to disengage from the connector pin and the prosthetic is removed longitudinally.

Chen makes no teaching which supplements the deficiencies of Capper, since Chen deals with a manual transverse adjustment, not rotational or bending. Accordingly, it is submitted that claims 4 and 10 are not obvious in light of Chen and Capper. Claims 11-14 are considered patentable for the reasons given in connection with claim 10 from which they depend.

Claim 15 is dependent on claim 9, which recites "the proximal and distal components ...in a fixed angle relation to the other ...in normal use, but with freedom to articulate away from the fixed angle relation when, in use, a bending force is applied to the prosthetic limb only when the force exceeds a threshold level." As stated above, neither Chen nor Capper make any teaching or suggestion regarding fixed angle relation, bending, or bending force. Thus, it is submitted that claim 15, and claims 16-19 dependent thereon, are not obvious in light of Chen and Capper.

Furthermore, independent claims 24 and 25 are not obvious in light of Chen and Capper. Chen does not disclose adjustment means for adjusting the threshold safe level of force on the prosthetic limb that will cause said at least one of bending and rotational articulation within the attachment apparatus. Capper does not provide any teaching which supplements the deficiencies of Chen. As explained above, the operation of the clutch in Capper is to prevent a locking gear 86 from rotating, thereby locking down a lock pin 60 of a prosthetic attachment locking assembly. The locking gear 86 is held in an axial locking position by a spring. When it is desired to remove the prosthesis, the gear 86 is pushed away from the locking position, so that the locking pin 60 is free to be removed axially. The spring 102 in Capper does not determine any level of force that will cause bending or rotational articulation within the apparatus. In Capper, there is no disclosure or suggestion of torque or bending on the limb that would cause bending or rotational articulation of the apparatus. In contrast, in Capper a button is pushed to disengage from the connector pin and the prosthesis is removed longitudinally.

New claim 26 is not obvious in view of Chen and Capper for the reasons given in connection with claims 24, 25, namely that Capper's spring 102 does not determine any level of force that will cause bending or rotational articulation within the apparatus.

Even if a person of ordinary skill in the art were to try to modify the apparatus of Chen in light of Capper, a person may try to modify Chen's apparatus to include a resiliently biased button for longitudinally removing one piece of apparatus from another. However, there is no teaching or suggesting in Chen of means for allowing a proximal and distal component to rotate or bend relative to the other only when a force above a certain threshold safe level is applied, nor is there is teaching or suggesting in Chen of adjustment means for adjusting such a threshold safe level of force. Thus claims 24 and 25 are not obvious in light of Chen and capper.

Conclusion

In view of the above amendments and remarks, allowance of all pending claims is respectfully requested.

A telephone conference with the Examiner is hereby requested. If at any time the Examiner wishes to discuss this application, he is invited to call V. Lawrence Sewell (Reg. No. 22,753) at (214) 349-8180, who is of Counsel to Attorney for Applicants.

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